The Clinical Investigator: Responsibilities in Medical Device Clinical Trials

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Objectives

- Define a medical device clinical investigator
- Explain the general and specific responsibilities of investigators
- Describe records and reporting requirements of investigators
Presentation Topics

- General responsibilities
- Specific responsibilities
- Records
- Inspections
- Reports
What is a Clinical Investigator (CI)?

- An individual who actually conducts a clinical investigation, under whose immediate direction the test article is administered, dispensed, or used.
General Responsibilities

- Follow the investigator agreement, the investigational plan, and applicable regulations
- Protect the rights, safety, and welfare of subjects
- Control devices under study
- Obtain informed consent

21 C.F.R. 812.100
Specific Responsibilities

- Obtain IRB and FDA approval
- Follow investigator agreement, investigational plan, and conditions of approval imposed by IRB or FDA
- Supervise device use
- Disclose financial interests
- Dispose of device

21 C.F.R. 812.110
Disqualification

- An investigator’s repeated or deliberate failure to comply with these requirements may result in disqualification from receiving investigational devices
Investigator Records

- All correspondence with another investigator, Institutional Review Board (IRB), sponsor, monitor, or FDA

21 C.F.R. 812.140(a)
Device Records

- Records of receipt, use, and disposition of device including:
  - Type and quantity of the devices, dates of receipt, and batch number or code mark
  - Name of all persons who received, used, or disposed of each device
  - Why and how many devices have been returned, repaired, or otherwise disposed of
Case Histories

- Exposure to the device
- CRFs and supporting data
  - Informed consent documents
  - Adverse device effects
  - Any relevant observations

21 C.F.R. 812.140(a)
Protocols

- All IRB approved amendments
  - Including approvals
- Documentation of protocol deviations and IRB and sponsor approvals

21 C.F.R. 812.140(a)
Record Retention

- Two years after study termination or completion
- Two years after records are no longer required to support marketing application

21 C.F.R. 812.140(d)
Records Custody

- Withdraw responsibility to maintain records
- Transfer custody to any other person who will accept responsibility
- Notice of transfer to FDA not later than 10 working days

21 C.F.R. 812.140(e)
Documentation

If it is not documented, it never happened!
FDA Inspections

- Occur at reasonable times and in a reasonable manner
- Permit records to be inspected and copied

21 C.F.R. 812.145
Investigator Reports

- Unanticipated Adverse Device Effects
- Withdrawal of IRB approval
- Progress reports
- Deviations from the investigational plan
- Informed consent
- Final report
- Other

21 C.F.R. 812.150
Adverse Effect

- Any adverse medical occurrence that may or may not be related to the investigational device

All adverse effects should be documented
Unanticipated Adverse Device Effect

- Any serious adverse effect that is possibly caused by or related to the investigational device:
  - Not previously identified in nature, severity, or degree, or
  - Any other unanticipated serious problem associated with a device

21 C.F.R. 812.3(s)
Investigator Responsibilities - AEs and UADEs

- Report Unanticipated AEs to the sponsor and IRB within 10 working days
- Maintain records of all AEs (anticipated or unanticipated)
- Follow the sponsor’s requirements for reporting and recording of AEs and UADEs
Study Deviations

- Document dates and reasons for any deviations from the study protocol
- Emergency deviations must be reported to the sponsor and IRB within 5 days
- Obtain prior approval from the sponsor, IRB, and FDA for changes or deviations from the investigational plan

21 C.F.R. 812.140(a)
A clinical investigator conducts a clinical investigation.

CI responsibilities are designed to:
- Protect human subjects
- Promote the collection of quality data